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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,762	09/22/2004	Joseph Anthony Jakubowski	X-15632	9672

25885 7590 04/13/2007
ELI LILLY & COMPANY
PATENT DIVISION
P.O. BOX 6288
INDIANAPOLIS, IN 46206-6288

EXAMINER

AUDET, MAURY A

ART UNIT	PAPER NUMBER
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1654

NOTIFICATION DATE	DELIVERY MODE
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04/13/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/508,762	Applicant(s) JAKUBOWSKI ET AL.	
	Examiner Maury Audet	Art Unit 1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: No amendments filed. (See 37 CFR 1.116 and 41.33(a)).

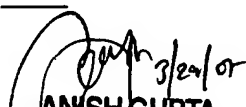
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.


ANISH GUPTA
PRIMARY EXAMINER

Continuation of 13. Other: Applicant's identical arguments pre-Final (no amendments) have been considered but again are not found persuasive. The rejection under 35 USC 112 1st enablement is maintained for the reasons of record. The Examiner has reviewed Applicant's specification/examples and maintains that these examples fail to provide any credible evidence of enablement to a using any GLP-1 compound to treat that which the literature teaches it is not enabled for. Contrary to Applicant's assertions, the Examiner's reliance on this literature as the basis upon which enablement rejection rests, is proper. Applicant has failed to provide credible evidence (e.g. via declaration or in some other form, since the specification lacks) or reasoning to 'suggest' that the literature has been wrong all these years. The Examiner believes Applicant's attempt to shift his burden back to an Office without the time or resources to carry out the appropriate test(s) on Applicant's untested CLAIMED invention lacks merit and is thus not persuasive.

To frame the present claims and issues for appeal:

Applicant's invention is to a using any GLP-1 to treat a person with gastroparesis.

The issue is whether a test that finds neutral results in a person without a disorder (gastroparesis) with a product (GLP-1) the literature says does not work for that disorder is credible evidence as to enablement for treating a person who actually has the disorder/symptoms? This would appear analogous to a test evaluating treating someone without diabetes using a product the literature says does not work for maintaining blood glucose levels in a person without diabetes and then arguing that since no effect on blood sugar was found in a nondiabetic patient that, contrary to the literature, this test 'suggests' this product should also maintain blood sugar levels in a diabetic patient. The Examiner again concludes, based on the reasoning above, that Applicant's traversal that the present test results (e.g. no change in person without the disorder) "suggest" the invention would work in someone with this disorder is simply not found persuasive as credible evidence of enablement.